

### **Remarks/Arguments**

Claims 1-4, 6-10, 63, 65 and 66 were examined and are rejected. Claims 5, 11-31, 42-53, 56-58, 61, 62, 64 and 67-69 were canceled in a previous response. Claims 32-41, 54, 55, 59 and 60 were previously withdrawn in response to a Restriction Requirement. Claims 1 and 3 have been amended. Claim 63 has not been amended. Accordingly, the next office action cannot be made final if a new reference is presented. Claims 1-4, 6-10, 63, 65 and 66 remain under examination in the application. Applicant respectfully requests that the amendment be entered pursuant to 37 C.F.R. 1.114.

Claims 1, 2, 63, 65 and 66 are rejected as allegedly being obvious under 35 USC §103(a) over Ehrlich (US 2,801,633), in view of Humphrey (US 5, 607, 401). See Office Action, p. 3.

Claim 1 (and claim 2 by its dependency) recites a lancet device comprising (a) a lancet including a seamless member having a first end and a second end with a length in between, the seamless member hollowed along a portion of its length, wherein first and second sharpened tips extend from the first end, the first and second sharpened tips spaced directly opposite each other on the seamless member and extending parallel to a longitudinal axis of the seamless member, and wherein the seamless member is itself sufficiently rigid to penetrate skin with the sharpened tips; and (b) a lancet holder arranged and configured on the second end of the lancet to move the lancet a penetration distance to penetrate the skin of a patient with the first and second sharpened tips, wherein the penetration distance is less than a length of the sharpened tips.

Claim 63 (and claims 65 and 66 by their dependency) recites a lancet including a partially hollow member having an outer wall, a first end, a second end and a length therebetween, wherein the outer wall defines a first ground surface and a second ground surface, the first and second ground surfaces each forming a gullet that extends

approximately 180 degrees about a longitudinal axis of the lancet forming at an intersection a first tip and a second tip at the first end, and wherein the outerwall is itself sufficiently rigid to draw fluid from a patient; and a lancet holder arranged and configured on the second end of the lancet to move the lancet to a penetration depth to penetrate the skin of a patient with the first and second tips, the penetration depth being less than a length of the gullet measured along the longitudinal axis.

The Examiner has failed to make a *prima facie* case of obviousness for both claims 1 and 63. As noted by the Examiner on page 3 of the Office Action, Ehrlich fails to disclose that the lancet is seamless. However, Ehrlich also fails to disclose that the lancet is a partially hollow member. Ehrlich describes the lancet of Fig. 8 as a blank that is rolled into a tube. Col. 5, lines 17-20. Accordingly, the entire length of the tube of Ehrlich is hollow. Humphrey also fails to disclose a lancet having a partially hollow member. Humphrey discloses polymeric piercing members in either of two broad classes: a solid lancet or a needle with at least one lumen. Humphrey also fails to disclose a partially hollow lancet. Therefore, the combination of Ehrlich and Humphrey does not teach, suggest or render obvious a partially hollow lancet.

In the Advisory Action dated June 21, 2010, the Examiner states that claim 1 recites "comprising." Applicants are not sure of the relevance of this statement. The Examiner also states that the combination of Ehrlich and Humphrey discloses "hollowed along a portion of its length" because the gullet is considered partially hollowed when the needle of Ehrlich as modified by Humphrey is made from a solid needle. Applicants disagree, as there is no teaching in either of Ehrlich or Humphrey to combine hollow and solid. Ehrlich only discloses hollow needles and Humphrey discloses either solid or hollow. Accordingly, one skilled in the art would combine the tips of Ehrlich with a hollow needle of Humphrey. There is no motivation for any other combination. Accordingly, the combination does not meet the claim limitation of a lancet including a seamless member hollowed along a portion of its length.

In any event, claim 63 recites a lancet including a partially hollow member having an outer wall, a first end, a second end and a length therebetween. The gullet is not included in the partially hollow member, making the Examiner's argument that the gullet is considered to be partially hollowed irrelevant to the claim language. Claim 1 has been amended to clarify that the partially hollow member is partially hollowed along its length, which is in between the ends. The tips extend from one of the ends. Accordingly, the Examiner's argument of a hollow gullet again does not have relevance to the language of claim 1.

Furthermore, both Ehrlich and Humphrey fail to disclose a penetration distance that is *less than a length* of the sharpened tips as required by the claims. Ehrlich discloses that the point members have a length of between 1 mm and 3 mm as pointed out by the Examiner. Ehrlich also discloses that the bends of the body of the lancet act as stops to limit penetration. Col. 5, lines 26-30. If the bends between tips stops penetration, clearly the entire length of the tip penetrates the skin and is only stopped by the bend. This clearly contradicts the claim language. Humphrey discloses hypodermic needles and lancets that make possible new types of phlebotomy devices and intravenous catheters. (Abstract; Col. 4, lines 16-35). Humphrey's needles allow for deeper penetration. (Col. 3, lines 25-26). The depth of the piercing process can be controlled so that the lancet stopped before "making contact with the supporting base structure. (Col. 8, lines 49-56) Therefore, the combination of Ehrlich and Humphrey does not teach, suggest or render obvious a penetration distance that is less than a length of the sharpened tips as recited in the claims.

In the Advisory Action the Examiner states "one of ordinary skill in the art would recognize that the depth of penetration should be about the same with the length of lancet point because it has been proven to be the effective depth of penetration." This is Applicants' argument exactly. This is why the combination clearly fails to meet the claim limitation, which requires the penetration distance to be *less than a length* of the sharpened tips. As noted by the Applicant in paragraph [0048], it was found that a

lancet driven a distance which is less than the length of the gullet minimizes the surface area of the lancet which penetrates into the patient's skin, minimizing patient discomfort.

Because the combination of Ehrlich and Humphrey fails to teach, suggest or render obvious at least these elements required by claims 1 and 63, Applicant respectfully submits that claims 1 and 63 and their dependent claims are in condition for allowance, notice of which is requested.

Claims 3, 4 and 6-10 are rejected as allegedly being obvious under 35 USC §103(a) over Ehrlich (US 2,801,633), in view of Ayres (US 3,906,932). See Office Action, p. 5.

Claim 3 (and claims 4 and 6-10 by their dependency) recites a lancet device comprising a lancet including a unitary stainless steel member which is hollowed along a portion of its length, the unitary stainless steel member including a first end and a second end, wherein the first end of the unitary member includes first and second ground surfaces which at least partially define first and second sharpened tips and each define a gullet between the sharpened tips; and a lancet holder arranged and configured on the second end of the lancet to move the lancet a penetration depth to penetrate the skin of a patient with the first and second sharpened tips, the penetration depth being less than a length of the gullet.

Again the Examiner notes that Ehrlich fails to disclose a seamless member. However, as noted above, Ehrlich fails to disclose a member hollowed along a portion of its length. Ehrlich describes the lancet of Fig. 8 as a blank that is rolled into a tube. Col. 5, lines 17-20. Accordingly, the entire length of the tube of Ehrlich is hollow. Ayres also does not teach or suggest a member which is hollowed along a portion of its length. The needle in Ayres was designed to penetrate the rubber stopper of a Vacutainer so that the hollow needle can transport blood from the wound to the Vacutainer, requiring the needle to be hollow along its entire length.

Furthermore, both Ehrlich and Ayres fail to disclose a penetration distance that is less than a length of the sharpened tips as required by the claims. Ehrlich discloses that the point members have a length of between 1 mm and 3 mm as pointed out by the Examiner. Ehrlich also discloses that the bends of the body of the lancet act as stops to limit penetration. Col. 5, lines 26-30. If the bends between tips stops penetration, clearly the entire length of the tip penetrates the skin and is only stopped by the bend. This clearly contradicts the claim language. Ayres also fails to disclose the penetration distance is less than a length of the sharpened tips. Ayres does not discuss penetrating skin. As clearly shown in Fig. 5, “an elevational view . . . showing the needle of the present invention penetrating a stopper of an evacuated tube,” the tips of the needle penetrate the entire stopper and come out the other end.

In the Advisory Action the Examiner states “one of ordinary skill in the art would recognize that the depth of penetration should be about the same with the length of lancet point because it has been proven to be the effective depth of penetration.” This is Applicants’ argument exactly. This is why the combination clearly fails to meet the claim limitation, which requires the penetration distance to be *less than* a length of the sharpened tips. As noted by the Applicant in paragraph [0048], it was found that a lancet driven a distance which is less than the length of the gullet minimizes the surface area of the lancet which penetrates into the patient’s skin, minimizing patient discomfort.

Because the combination of Ehrlich and Ayres fails to teach, suggest or render obvious at least these elements required by claim 3, Applicant respectfully submits that claim 3 and its dependent claims 4 and 6-10 are in condition for allowance, notice of which is requested.

For the reasons set forth above, Applicant traverses the Examiner’s rejections and respectfully submits that all pending claims are allowable. Applicant requests the Examiner’s early examination of the pending claims in the present application. In the event that the Examiner deems a telephonic discussion would be helpful in advancing

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the prosecution of the present application, Applicants respectfully request the Examiner to contact Applicants' representative at (248) 244-0163.

Respectfully submitted,

YOUNG BASILE  
HANLON & MACFARLANE PC



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By: Francine B. Nesti, Reg. No. 53376  
Attorneys for Applicant